

## **REMARKS**

### **I. Status of Claims**

After entry of the present amendment, claims 1-39 are pending in the application. Claims 1 and 38 are presently amended. No new matter is added by way of the amendments.

Specifically, claim 2 is amended to add a missing parenthesis in “4-(phenyldiazenyl)phenyl”.

Claim 38 was amended to provide a nexus between the preamble and the claim steps.

### **II. Rejections under 35 U.S.C. § 112-2<sup>nd</sup> Paragraph**

Claim 38 has been amended to provide a nexus between the preamble and the claim steps.

### **III. Rejections under 35 U.S.C. § 102/103**

Claims 1-10, 18-23, 33 and 36 have been rejected under 35 U.S.C. § 102(e) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Theaker, et al. [2002/0102571 (2002)].

With respect to claims 1-10 and 18-23, the Examiner makes reference to paragraph [0032] of Theaker et al. Patent Application number 2002/0102571. Theaker et al. describes a molecular beacon with 2'-O-substituted RNA. The substitutions are present to ensure that there is no degradation. Theaker et al. describes a beacon with a configuration with this general structure: F-stem-loop-stem-Q, wherein F is a fluorophore and Q is a quencher. The loop is complementary to the target sequence so when it hybridizes to the target, it attaches target-to-loop, and the stem ends open up (spatially separate) which in turn emits a signal. The loop region would have to be nuclease resistant in order for this to work. An example of Theaker et al.'s “2-methyl RNA Molecular Beacon” is provided in the referenced paragraph [0032].

The Examiner's argument is that the Applicant's “cleavage domain” limitation is inherent in the loop portion of Theaker et al.'s 2-methyl RNA Molecular Beacon. The

Applicant respectfully notes that the beacon described by Theaker would not work if a cleavage domain existed. The purpose of a molecular beacon is to provide a dual-labeled probe that does not cleave, as Theaker et al. notes in paragraphs [0016] and [0017]. Theaker uses the 2'OMe to make the beacon more nuclease resistant, while Applicant is using 2'OMe to restrict the intended cleavable domain to a specific internal sequence. Therefore, Theaker et al.'s non-cleavable beacon contains no cleavage domain, which is present in Applicant's claims, and teaches away from Applicant's invention.

Likewise, claims 33 and 36 refer to a kit with a cleavage domain limitation. The Examiner references paragraph [0018] of Theaker as anticipating claims 33 and 36, but for the reasons outlined above, Applicant's kit is outside of any kit contemplated by Theaker.

In conclusion, Applicant maintains that the cleavage domain limitation is not disclosed in Theaker. Anticipation requires that each and every element of the rejected claim be disclosed in a single prior art reference. See, M.P.E.P. § 2131. Every element of the claimed invention must be literally present, arranged as in the claim. *Perkin Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir. 1984). A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, in view of the above amendments and remarks, Applicants respectfully request that the § 102 rejection of claims 1-10, 18-23, 33 and 36 over Theaker be withdrawn.

In response to these § 103 rejections, Theaker does not teach utilizing a nucleic acid composition with a cleavage domain. Theaker actually teaches away from any utility of a cleavage domain in their proposed invention. The Applicants respectfully remind the Examiner that "in determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been

obvious, but whether the claimed invention as a whole would have been obvious.” (emphasis originally present). See, M.P.E.P. § 2131. Claims 1-10, 18-23, 33 and 36 require that the nucleic acid be cleavable. Applicants submit that no reference or combination of references would make this claim limitation obvious to one of ordinary skill in the art. Theaker does not provide a method wherein the nucleic acid is cleaved as Theaker is concerned with a field of art, hybridization assays, that is distinct from Applicant’s field of art, ribonucleases detection assays, and therefore a person of reasonable skill in the art would not have turned to Theaker’s invention as a solution to the problem that Applicant’s invention resolves. Thus, Theaker would not render obvious any of Applicant’s claims that are distinguishable from Theaker *per se*. Accordingly, the aforementioned obviousness rejection is moot as it is asserted over claims 1-10, 18-23, 33 and 36.

#### **IV. Non-Statutory Obviousness-type Double Patenting Rejection**

The Applicant notes the rejection, and has included a terminal disclaimer in compliance with 37 CFR 1.321(c) to overcome the rejection.

#### **V. Conclusion**

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner’s Amendment, the

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Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

By   
John Petravich

Registration No.: 53,460  
Integrated DNA Technologies, Inc.  
8180 McCormick Blvd.  
Skokie, IL 60076  
(847) 745-1699  
(847) 745-1710 (Fax)  
Attorney/Agent For Applicant